510(K) SUMMARY

OCT 5 2012

Corentec Co., Ltd.

Bencox II Stem & Bencox Metal Head

July 10th, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Corentec Co., Ltd.
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Bencox II Stem & Bencox Metal Head
Common Name:	Hip Prosthesis
Classification Regulations:	21 CFR 888.3358; 888.3390
Class:	II
Product Codes:	LPH; KWY
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The Bencox Hip System is intended for cementless use in total or partial hip arthroplasty in primary or revision surgery for the following conditions:

a. Non-inflammatory degenerative joint disease, such as avascular necrosis, osteoarthritis, traumatic arthritis
b. Inflammatory degenerative joint disease, such as rheumatoid arthritis
c. Treatment of non-union, femoral neck fracture and trochantric fractures of the proximal femur with head involvement, unmanageable using other techniques
d. Patients with failed previous surgery where pain, deformity, or dysfunction persists
e. Revision of previously failed total hip arthroplasty

DEVICE DESCRIPTION

Bencox II Stem cleared under K103431 is modified at the proximal neck region. The other aspects of design / material / specification / manufacturing & sterilization / packaging are not altered and remain the same as discussed in K103431. The component is manufactured from Ti-6Al-4V alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401); Co-Cr-Mo alloy conforming to ASTM F1537 Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants.

Bencox Metal Head is cleared under K103431 & K112019 with the neck lengths of small, medium and large. This submission includes extra large (XL) neck length as an inclusion to the existing specification. The other aspects of design / material / specification / manufacturing & sterilization/packaging are not altered and remain the same as discussed in K103431 & K112019. The component is manufactured from Co-Cr-Mo alloy conforming to ASTM F1537 *Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants.*

SUBSTANTIAL EQUIVALENCE

The Bencox II Stem & Bencox Metal Head are substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent, as below,

- **Corentec Co., Ltd.**, Coren Total Hip System (*now renamed as Bencox Total Hip System*) cleared under K103431
- **Corentec Co., Ltd.**, Bencox Bipolar Cup System cleared under K112019

PERFORMANCE DATA

The Bencox II Stem neck change & Bencox Metal Head components were subjected to a series of testing protocols to document the performance of the components and to demonstrate substantial equivalence for fatigue strength and range of motion and the included methods are described in the standards, ISO 7206-4, ISO 7206-6 & ISO 21535.

The Bencox Metal Head-XL was also tested with Bencox ID Stem (machined) & Bencox ID Stem (forged). Bencox II Stem neck change & Bencox Metal Head-XL components performed either similar or better than the predicate devices cleared under K103431 & K112019.

STERILIZATION & PACKAGING

Sterilization validation as per ISO 11137 – 1 & 2 Sterilization of health care products – Radiation ensures sterility of the components for an SAL of 10^{-6}. Both Bencox II Stem & Bencox Metal Head and the predicate devices cleared under K103431 & K112019 have same shelf life. Following sterilization, packaging was subjected to sterile barrier testing to validate a shelf life of 5 years for both components.

Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy. Overall, the Bencox II Stem neck change & Bencox Metal Head-XL has similarities to the predicate devices with the same intended use, same fundamental scientific technology, same operating principles, same materials and are supplied Sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% Mr. J.S. Daniel
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Seocho Gu, Seoul, Korea 137-040

OCT 5 2012

Re: K122099
Trade/Device Name: Bencox II Stem & Bencox Metal Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH; KWY
Dated: September 4, 2012
Received: September 6, 2012

Dear Mr. Daniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122099

Device Name: Bencox II Stem & Bencox Metal Head

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e. Revision of previously failed total hip arthroplasty

Prescription Use: X (Per 21 CFR 801 Subpart D)	AND / OR	Over-The Counter Use: ——— (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122099